UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

EILEEN F. DONOVAN and
TIMOTHY DONOVAN,

Plaintiffs,

-vs- 03-CV-0376C(SC)

CENTERPULSE SPINE-TECH INC.,

Defendant.

APPEARANCES: HODGSON RUSS LLP (Ryan K. Cummings, Esq., of Counsel), Buffalo, New York for Plaintiffs.

HURWITZ & FINE, P.C. (Harry F. Mooney, Esq., of Counsel), Buffalo, New York for Defendant.

INTRODUCTION

Plaintiffs brought this action to recover damages for injuries suffered by plaintiff Eileen Donovan following spinal fusion surgery in February 2001. Mrs. Donovan's surgeon utilized the Centerpulse Spine-Tech Silhouette Spinal Fixation System ("SSF System"), an implant system of rods and screws used to correct spinal deformity and facilitate the process of spinal fusion. On July 27, 2001, x-rays of Mrs. Donovan's spine revealed that one of the six screws implanted in her vertebra had fractured. Mrs. Donovan underwent additional surgery on August 6, 2001 to have the SSF System removed, and alleges that she suffered permanent disabling injuries as a result of the broken screw. Plaintiffs have moved for partial summary judgment on liability (Item 64), and defendant has cross-moved

for summary judgment (Item 70) and to preclude, pursuant to Fed. R. Evid. 702, the testimony of plaintiff's proposed expert witness (Item 79).

BACKGROUND and FACTS

Plaintiffs commenced this action on May 9, 2003, alleging a single cause of action on behalf of Mrs. Donovan and a derivative cause of action on behalf of Mr. Donovan.[1] Specifically, plaintiffs alleged that Mrs. Donovan's injuries were caused "wholly or in large part to the interval fracture of the implanted screw, which resulted solely to (sic) the defective design and/or manufacture of the same screw, and due to no negligence on Ms. Donovan's part." Item 1, ¶ 11.

According to the parties' statements, pursuant to Local Rule 56.1, of facts not in dispute[2], Mrs. Donovan was injured in a fall on February 25, 2000. MRI imaging in March 2000 revealed bulging discs at L4-5 and L5-S1[3]. Mrs. Donovan initially underwent conservative treatments, including physical therapy and cortisone injections, but they did not provide lasting relief. On February 21, 2001, Mrs. Donovan underwent a lumbar laminectomy and spinal fusion at L3-S1. The surgery involves the passage of screws into the pedicles[4] on either side of the spine, and the placement of a rod along the spine

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[1] Plaintiffs filed an amended complaint on June 11, 2003 for the purpose of discontinuing the action against defendant Centerpulse USA, Inc. (Item 2).

[2] Plaintiffs' Rule 56 statement is docketed as Item 67. Defendant's statement is docketed as Item 72. Plaintiffs' response is docketed as Item 92, and defendant's response is docketed as Item 95 .

[3] "L4-5" refers to the fourth and fifth vertebrae of the lumbar spine, while "S1" refers to the first vertebra of the sacral spine.

[4] The pedicles are two bony structures that extend from the vertebral body on either side of the spinal column.

through the screws. Plaintiff's surgeon, Dr. Loubert Suddaby, utilized the Centerpulse SSF System. Following the surgery, Mrs. Donovan complained of numbness and pain in her left leg. X-rays of the operative site, taken on July 3, 2001, revealed a fracture of the right S1 implanted screw. On August 6, 2001, Mrs. Donovan underwent additional surgery to have the entire SSF System removed, except for a portion of the fractured pedicle screw imbedded in her spine. Dr. Suddaby determined that spinal fusion had not occurred.

Plaintiff Eileen Donovan testified in a deposition that prior to her surgery, she reviewed and signed a consent for treatment. Item 76, Exh. K ("Donovan Dep.") p. 70. She also discussed the surgery with Dr. Suddaby. *Id.,* p. 74. Dr. Suddaby advised Mrs. Donovan that the surgery may not succeed. *Id.*, p. 75. The consent form stated that a possible complication of the surgery is malfunction or breakage of the equipment, although Mrs. Donovan denied that Dr. Suddaby informed her of this. *Id.,* pp. 80-81. Following the surgery, Mrs. Donovan experienced a "grinding" pain in the left side of her lower back. *Id.,* p. 87. She also continued to experience a stabbing pain that she felt prior to the surgery, and that continued through her thigh and down her left leg. *Id.* Additionally, Mrs. Donovan lost feeling in her left kneecap, and the numbness has progressed down her leg. *Id.,* pp. 88, 100. That pain has grown progressively worse since the surgery and has never resolved, although the grinding pain stopped after the implants were removed. *Id.,* pp. 90-91. Following the second surgery, Mrs. Donovan did not return to Dr. Suddaby. *Id.,* p. 102.

In support of their motion, plaintiffs submitted the deposition testimony of Dr. Suddaby. Item 64, Exh. H ("Suddaby Dep."). Dr. Suddaby stated that Mrs. Donovan was

referred to him for numbness and weakness in her left leg following an injury. *Id.,* p.14-15. He examined her on April 20, 2000 and found that she "had pain on movement of her spine in all spheres" and was "morbidly obese," meaning that the excess weight she carried was detrimental to her health and well-being. *Id.,* pp. 15-16. On October 10, 2000, Mrs. Donovan reported to Dr. Suddaby that she had experienced no specific benefit from pain management and epidural cortisone injections. *Id.,* p. 23. Dr. Suddaby discussed with Mrs. Donovan surgical interventions known as laminectomy and spinal fusion. He also discussed the risks of the surgery and advised Mrs. Donovan that obesity creates a risk of non-union of the fusion, a higher risk of infection, and makes the surgery technically more difficult for the surgeon. *Id.,* p. 66. Mrs. Donovan nonetheless agreed to the surgery.

Dr. Suddaby performed Mrs. Donovan's spinal fusion surgery on February 21, 2001 and utilized the SSF System. It was a system Dr. Suddaby used in the past, and he was generally satisfied with it. Suddaby Dep., p. 42. Six screws were used in the procedure for Mrs. Donovan. *Id.,* p. 52. Following the surgery, Dr. Suddaby saw Mrs. Donovan for follow-up care. She complained of pain, numbness, and hyperesthesia, or heightened sensitivity of the skin, in her left leg. Dr. Suddaby did not find this unusual, as that was the leg in which Mrs. Donovan experienced most of her symptoms prior to surgery. *Id.,* pp. 60-62. Post operative x-rays revealed that the right screw was medially placed, meaning that "the screw is placed more towards the center of the midline of the spine than to the lateral part of the spine." *Id.,* p. 64. However, Dr. Suddaby concluded that this medial position did not account for plaintiff's symptoms on the left leg. *Id.,* p. 63. Dr. Suddaby further

stated that medial placement of the screw can "irritate a nerve and cause pain or numbness or weakness," but the placement of the right sacral screw would not cause problems on the left leg. *Id.,* p. 64.

In May 2001, Mrs. Donovan reported diminished reflexes in the right ankle and left knee. Suddaby Dep., p. 67. These findings indicated the "potential for irritation or dysfunction of one of the nerve roots that subtend those reflexes." *Id.,* p. 67. Dr. Suddaby suspected that the absent right ankle reflex could be related to the medially placed right sacral screw, but Mrs. Donovan's fusion seemed to be progressing and she stated that she could live with the symptoms. *Id.,* p. 68. Dr. Suddaby prescribed the use of a brace and an electromagnetic bone stimulator as part of her post-surgical care. *Id.,* pp. 69-70. On July 7, 2001, Dr. Suddaby reviewed x-rays of Mrs. Donovan's lumbar spine and saw evidence of the fracture of one of the screws. *Id.,* p. 72. He stated that a fracture of the screw can occur because of metal fatigue, weakness, or some other defect in the screw. *Id.* Dr. Suddaby stated that the most common reason for a screw fracture is the failure of the "fusion to support the bone" and explained that "the metal over a period of time will fracture from continued flexing and extending of the spine." *Id.,* p. 73. In this case, Dr. Suddaby stated that the "fusion did not progress . . . meaning that the bones were not solid and immobile within a period of three to four months and with the progression of time, the metal eventually will fail." *Id.* Dr. Suddaby stated that he warned Mrs. Donovan of this risk, and saw no evidence of a defect in the metal screw itself or in its design, or in the SSF System. *Id.,* pp. 73-74.

On August 6, 2001, Dr. Suddaby performed surgery to remove the spinal hardware. Suddaby Dep., p. 75. The right sacral screw was fractured at the midpoint of the shaft. *Id.* Part of the screw remained in the bone, as removal would have required the drilling away of additional bone. *Id.,* p. 76. In his operative report, Dr. Suddaby noted "minimal fusion massed bilaterally," meaning less fusion than would have been expected over that period of time, and "residual lumbar instability." *Id.,* p. 78. In his opinion, this was the cause of much of plaintiff's pain, coupled with spinal stenosis. *Id.,* pp. 78-79. Dr. Suddaby stated that the instability of the spine was "a significant component" of plaintiff's post-operative pain, along with other "possible things such as perineural scarring and possible irritation of her nerve roots, inflammatory reasons" as part of the healing process. *Id.,* p. 79.

In October 2001, Mrs. Donovan was still experiencing some pain, despite the removal of the hardware. Dr. Suddaby stated that Mrs. Donovan's post-operative pain was likely caused in part by the loose hardware, but that was not the only cause, as removal of the hardware did not rectify the problem. *Id.,* p. 80. In Dr. Suddaby's opinion, plaintiff's pain was caused by the non-union of the fusion and continued instability of the spine, along with the other factors previously discussed. *Id.,* p. 81. Dr. Suddaby also stated that the screw fragment in plaintiff's pedicle is not impinging on a nerve. *Id.,* p. 86. Dr. Suddaby stated that it is "possible" that the fractured pedicle screw could have interfered with the union of the fusion generally, *id.,* p. 114, or it was equally possible that it had nothing to do with the non-union. *Id.,* p. 126.

Assuming compliance by plaintiff with post-operative instructions, Dr. Suddaby attributed the fracture of the screw to metal fatigue. He explained that it is a "race between the bone fusing and the metal fatiguing. That goes to say that in any of these fusion surgeries, if bony fusion does not occur, ultimately at some point in time it is expected that the instrumentation will fail. And exactly when that point is achieved is variable from human being to human being." Suddaby Dep., p. 122. Dr. Suddaby also explained that length of time before fusion is achieved depends on the activity and size of the person and the number of spinal levels fused. *Id.,* p. 123. Dr. Suddaby stated that out of hundreds of spinal fusion surgeries he had performed over the years, he had seen approximately "half a dozen or more of these fractures . . . ." *Id.,* p. 84. Dr. Suddaby no longer uses the SSF System, and switched to a different spinal fusion system since the time of Ms. Donovan's surgery because others were easier to use. *Id.,* p. 88. He has seen fractures of the pedicle screws in those systems as well. *Id.*

Plaintiffs also submitted the deposition testimony of Angela Hillyard, Director of Product Development for defendant Centerpulse. Item 64, Exh. K ("Hillyard Dep."). Ms. Hillyard testified regarding the testing of the pedicle screws for approval by the United States Food and Drug Administration ("FDA"). She stated that the average time for a spinal fusion to occur following surgery is 12 months, and that during that 12-month period, there would be between 1 and 2.5 million stress cycles on the component. *Id.,* p. 37. A stress cycle is "the loading and unloading action on the screw construct or component." *Id.* For ease of reference, Ms. Hillyard compared one cycle to the bending and straightening of a paperclip. *Id.* The screws used in the SSF System were tested

according to the American Society of Testing Materials ("ASTM") provisional standard PS 5-94 and draft standard F-04.25.03 and were tested to 5 million cycles. *Id.,* pp. 38-41. If a product did not withstand at least one million cycles in testing, it is not likely to last the average 12 months for a fusion to occur. *Id.,* p. 41. Ms. Hillyard stated that the product insert for the SSF System provides that the product is contraindicated for use in obese persons, but she is aware that the product is nonetheless used in obese patients. *Id.,* p. 47. Ms. Hillyard also stated that ASTM testing standards are used to establish a testing protocol, not to define the life of the product. *Id.,* p. 49. Additionally, Annette Doxon, defendant's Director of Quality, testified that the pedicle screws used in Mrs. Donovan's surgery were manufactured by Remmele Engineering. Item 64, Exh. J, p. 24. The lot of screws was inspected and checked for quality control prior to packaging. *Id.,* p. 30.

In further support of their motion for summary judgment, plaintiffs submitted the expert opinion of Ronald J. Parrington, a materials engineer who has worked in the field of failure analysis in metallic and non-metallic materials.[5] Mr. Parrington examined the SSF System hardware that was removed from Ms. Donovan and determined that the screw fractured as a result of fatigue. Item 65, ¶ 29. Mr. Parrington was able to determine, based on a microscopic analysis of the fatigue striations on the screw itself, that the screw underwent approximately 100,000 stress cycles from the time of implantation until the fatigue was initiated. Thereafter, the screw fractured after approximately 16,000 cycles. *Id.,* ¶¶ 41-42. Mr. Parrington stated that according to ASTM standard 1717-96, 5,000,000 cycles represents the number of loading cycles that a person might experience within two

[5] Defendant has moved to exclude Mr. Parrington's testimony under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) (Item 79).

years based on moderate activity. *Id.,* ¶ 44. He concluded that the screw that fractured in Ms. Donovan's spine failed in less than 1,000,000 cycles. *Id.,* ¶ 50.

In his deposition, Mr. Parrington testified that he never took any courses in anatomy or biomechanical or biomedical engineering. Item 77, Exh. N ("Parrington Dep."), pp. 30-32. This case is one of two he has investigated involving medical devices used in spinal surgery. *Id.,* p. 44. He has never had training with respect to the use of hardware in spinal surgery or attended any seminars on the subject. *Id.,* p. 62. He did not speak to Mrs. Donovan or review the deposition testimony of Dr. Suddaby prior to preparing his report. *Id.,* p.76. Mr. Parrington was unable to say whether patient or other medical factors could have contributed to the fracture of the pedicle screw. *Id.,* p. 111.

In support of its motion, defendant has submitted the report of Dr. Robert Lifeso, an orthopedic surgeon. Item 73, Exh. E. Dr. Lifeso performed a physical examination of Mrs. Donovan and reviewed all available medical records and the deposition of Dr. Suddaby. Dr. Lifeso concluded that the pedicle screw broke due to a failure to achieve spinal fusion, and this non-union was caused by many possible factors, including Mrs. Donovan's weight, the length of the lumbar fusion from L3 to the sacrum, the use of insufficient bone graft, the lack of screw placement at L5, perioperative treatment with steroids, and the placement of the right pedicle screw in the lateral gutter of the spinal canal, rather than the pedicle itself. *Id.,* p. 32. Dr. Lifeso also opined that the fracture of the right screw at S1 did not cause a significant neurological defect, as Mrs. Donovan's complaints prior to and after surgery related to her left leg. *Id.,* p. 33.

Defendant also submitted an expert report of Brad James, a metallurgical engineer specializing in failure analysis, materials science, fracture mechanics, and design. Item 79, Exh. E. Dr. James examined the pedicle screw implanted in Ms. Donovan and opined that it fractured "due to fatigue crack initiation and growth." *Id.,* p. 3. However, Dr. James opined that the fatigue fracture was not caused by a metallurgical defect, but due to "cyclic *in vivo* loads that exceeded those for which it was designed, because sufficient bone fusion did not occur to support the screw, and because the screw was not otherwise supported by bone." *Id.* In a declaration, Item 96, Dr. James stated that the ASTM standards cited by plaintiff's expert are not performance standards. By their express terms, the ASTM standards are not intended "to define levels of performance," but only to "outline testing procedures that can be followed to provide a basis for mechanical comparison among spinal implant assemblies." Item 96, ¶¶ 9-10 (internal citation, quotation, and emphasis omitted). The tests do not duplicate the loading scenarios of the human body, and thus cannot account for factors like a patient's weight or insufficient healing. *Id.,* ¶ 10.

In a supplemental declaration dated August 8, 2008, Item 99, Dr. James criticized the methodology employed by plaintiff's expert, Mr. Parrington. Specifically, Dr. James stated that Mr. Parrington's estimate of fatigue initiation after approximately 100,000 cycles and 16,000 cycles between fatigue initiation and fracture is not based on proper methodology and cannot be properly calculated without knowing the specific stresses placed on the screw. *Id.,* ¶ 14.

DISCUSSION

1. Cross Motions for Summary Judgment

Plaintiffs contend that they are entitled to summary judgment on a variety of theories. Specifically, they argue that defendant is strictly liable in that the pedicle screws in the SSF System were defectively designed and manufactured, and that defendant failed to warn plaintiffs of the dangers associated with the SSF System. Plaintiffs also contend that defendant is liable for the negligent design of the pedicle screw and for the breach of the implied warranty that the SSF System was reasonably fit for its intended purpose.

Defendants argue in response to the motion that plaintiff has set forth theories of liability in their motion that were not raised in the complaint, including strict products liability, failure to warn, and breach of warranty. Defendant contends that plaintiffs have failed to establish that the SSF System was defectively designed or manufactured or, significantly, that Ms. Donovan's injuries were caused by the fracture of the pedicle screw. Defendant also contends that plaintiff has failed to establish that the warnings provided by defendant were inadequate or that the SSF System was unfit for its intended purpose. Accordingly, defendant seeks summary judgment dismissing plaintiffs' complaint.

The court notes that the plaintiffs have not clearly stated distinct causes of action. The complaint provides simply that Mrs. Donovan's "present condition is due wholly or in large part to the interval fracture of the implanted screw, which resulted solely to the defective design and/or manufacture of the same screw, and due to no negligence" on plaintiff's part. Item 1, ¶ 11. As the court reads the complaint, plaintiffs have attempted to assert claims for strict products liability and possibly negligence. *See Colon ex rel*

Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001) ("Courts have noted that, for the purposes of analyzing a design defect claim, the theories of strict liability and negligence are virtually identical."); *Saladino v. Stewart & Stevenson Servs., Inc.*, 2007 WL 4285377, at *5 (E.D.N.Y. December 3, 2007) ("New York courts have treated the differences between negligence and strict liability as inconsequential."). As the negligence and strict products liability claims are examined using the same analytical framework, the terminology is unimportant. *See Ramos v. Simon-Ro Corp.*, 2008 WL 4210487, *9 (S.D.N.Y. September 11, 2008) (single analysis of design defect claim and negligent design claim); see also *G.E. Capital Corp. v. A.O. Smith Corp.*, 2003 WL 21498901, at *4 (S.D.N.Y. July 1, 2003) ("[P]laintiff must make out the same prima facie case regardless of whether the claim is based in strict liability or negligence."); *Searle v. Suburban Propane Div. of Quantum Chem. Corp.,* 700 N.Y.S.2d 588, 591 (App.Div.2000) ("[I]n a design defect case, there is almost no difference between a prima facie case in negligence and one in strict liability." (Internal quotation and citation omitted.)). Additionally, the court notes that the complaint does not contain facts alleging either a failure to warn or the breach of an implied warranty. However, to be thorough, the court will address those theories as well. As the issue of causation is central to the analysis of all plaintiff's claims, with the exception of the claim for failure to warn, the court will discuss those theories collectively.

A. Summary Judgment Standard

The standard for determining a motion for summary judgment is well settled. A motion for summary judgment must be granted when the record presents no genuine issue of material fact and, based upon the undisputed facts, the moving party is entitled to

judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The existence of a factual dispute between the parties will not prevent the entry of summary judgment unless it is a "*genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). An issue of fact is genuine only where the evidence taken as a whole would allow a reasonable jury to return thereupon a verdict in favor of the non-moving party; whether such issue is material is governed by applicable substantive law. *Id.* at 248. In considering a motion for summary judgment, the court's duty is to determine whether a genuine issue of material fact exists which must proceed to trial. *Id*. at 249. In doing so, the court must accept as true evidence provided by the non-moving party and, in considering the evidence as a whole, any ambiguities must be resolved and all reasonable inferences therefrom must be drawn in the light most favorable to such party. *Id*. at 255; *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 157 (1970). When cross motions for summary judgment are filed, "the standard is the same as that for individual motions for summary judgment." *Natural Res. Def. Council v. Evans*, 254 F. Supp. 2d 434, 438 (S.D.N.Y. 2003). "The court must consider each motion independently of the other and, when evaluating each, the court must consider the facts in the light most favorable to the non-moving party." *Id.* (citing *Morales v. Quintel Entm't, Inc.*, 249 F.3d 115, 121 (2d Cir. 2001)).

B. Design Defect, Negligence, and Breach of Warranty

In this diversity case, the court applies the substantive law of New York. *See Underwood v. B-E Holdings, Inc.,* 269 F. Supp. 2d 125, 130 (W.D.N.Y. 2003). In New York, there are three separate bases for strict products liability:

> (1) a manufacturing defect, which results when a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm; (2) a warning defect, which occurs when the inadequacy or failure to warn of a reasonably foreseeable risk accompanying a product causes harm; and (3) a design defect, which results when the product as designed is unreasonably dangerous for its intended use.

McCarthy v. Olin Corp., 119 F.3d 148, 154-55 (2d Cir.1997) (internal citations omitted); *see also Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983). Plaintiffs have arguably alleged that the pedicle screw was defectively designed and manufactured under theories of both negligence and strict liability. It is well settled that in New York, "whether the action is pleaded in strict products liability, breach of warranty or negligence," the plaintiff in a products liability case bears the burden of establishing "that a defect in the product was a substantial factor in causing the injury . . . ." *Tardella v. RJR Nabisco, Inc.*, 576 N.Y.S.2d 965, 966 (App. Div. 1991)(citing *Rosado v. Proctor & Schwartz*, 484 N.E.2d 1354 (N.Y. 1985)); *Heller v. U.S. Suzuki Motor Corp.*, 477 N.E.2d 434 (N.Y. 1985)); *see also Sita v. Danek Medical, Inc.*, 43 F. Supp. 2d 245, 252 (E.D.N.Y. 1999); *Gilks v. Olay Co., Inc.*, 30 F. Supp. 2d 438, 443 (S.D.N.Y.1998) (interpreting New York law).

Here, plaintiffs have failed to offer evidence that the fractured pedicle screw was a substantial cause of Mrs. Donovan's injuries.[6] Under New York law, when the determination of whether an injury was caused by some event or conduct is "presumed not to be within common knowledge and experience," competent medical opinion evidence is

[6] Plaintiffs have also failed to offer evidence of a feasible, safer design alternative, which is essential to survive a motion for summary judgment in a design defect case. *See Fane v. Zimmer, Inc.,* 927 F.2d 124, 128 (2d Cir. 1991); *Prohaska v. Sofamor, S.N.C.,* 138 F. Supp. 2d 422, 443 (W.D.N.Y. 2001).

necessary to enable a jury to find the requisite causation. *Fane v. Zimmer, Inc.,* 927 F.2d 124, 131 (2d Cir. 1991) (citation omitted).

Plaintiff's only evidence of causation is offered through the deposition testimony of Dr. Suddaby, the doctor who performed Mrs. Donovan's surgeries. A thorough review of Dr. Suddaby's testimony reveals a lack of support for plaintiff's position. At no time did Dr. Suddaby state that Mrs. Donovan's injuries were substantially caused by either the SSF system or its component parts. Dr. Suddaby identified no permanent injuries as a result of the spinal fusion surgery, only a continuation of the pain Mrs. Donovan experienced before the surgery. Dr. Suddaby observed no defect in the screw itself, and concluded that Mrs. Donovan's post-operative pain was caused only in part by the "loose hardware." Suddaby Dep., p. 80. Dr. Suddaby noted that Mrs. Donovan's pain continued after the removal of the hardware, leading him to conclude that the loose hardware was not the significant cause of her continuing injuries. Rather, Dr. Suddaby stated that the "significant component" of Mrs. Donovan's continuing pain is the result of non-union of the fusion, lumbar instability, and spinal stenosis. *Id.,* pp. 79-81. Dr. Suddaby also stated that the screw fragment remaining in plaintiff's spine was not impinging on any nerves. He expressed no definite opinion whether the fractured screw could have contributed to the failure of the spinal fusion.

Plaintiffs have taken great liberties with their characterizations of Dr. Suddaby's testimony. Notably, they stated in their memorandum of law, contrary to the evidence in the record, that "Dr. Suddaby has opined that the failure of the screws was a substantial

factor in causing Eileen Donovan's injuries." Item 68, pp. 17-18.[7] To the contrary, Dr. Suddaby stated that plaintiff's pain was primarily caused by the non-union of the fusion and continued instability of the spine, and only in part by the loose hardware, a condition which was subsequently removed. Suddaby Dep., p. 81. To conclude, based on the testimony of Dr. Suddaby, that Mrs. Donovan's permanent and continuing injuries were caused in substantial part by the SSF System or the pedicle screws would require a trier of fact to engage in speculation and conjecture, and to completely disregard Dr. Suddaby's testimony to the contrary.

Plaintiffs' failure to offer proof of causation defeats their motion for summary judgment on the strict products liability, negligence, and breach of implied warranty claims.[8] Additionally, this failure of proof requires the granting of defendant's motion dismissing the claims. Accordingly, plaintiffs' motion is denied, and defendant's motion for summary judgment dismissing these claims is granted.

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[7] Plaintiffs further mischaracterized Dr. Suddaby's testimony when they stated in their memorandum of law that the rate of breakage of SSF System pedicle screws in Dr. Suddaby's experience was "unusual" and that Dr. Suddaby stopped using the SSF system as a result of his experiences. Item 68, p. 13. The rate of fracture was never described by Dr. Suddaby as "unusual," and he testified that the primary reason he switched to another system was ease of use. Suddaby Dep., p. 88. Additionally, plaintiffs stated that Dr. Suddaby's "disappointment with the [SSF] System is underscored by the disastrous results he had with them in his patients." Item 68, p. 19. Dr. Suddaby neither expressed disappointment with the SSF System nor characterized his results as disastrous. In fact he testified that he experienced screw fractures with other systems as well. Suddaby Dep., p. 88.

[8] As with plaintiffs' claims of strict liability and negligence, a claim for breach of implied warranty also requires the plaintiff to establish causation. *See Nealy v. U.S. Surgical Corp.*, 587 F. Supp. 2d 579, 584 (S.D.N.Y. 2008); *Clarke v. Helene Curtis, Inc.*, 742 N.Y.S.2d 325, 327 (App. Div. 2002) ("The defendant established its prima facie entitlement to summary judgment by demonstrating that there was no causal relationship between its product and the plaintiff's disease, an essential element of the cause of action to recover damages for breach of implied warranty." (citations omitted)).

C. Failure to Warn

Plaintiffs also contend that defendant failed to warn of the dangers associated with the SSF System. "Under New York law, a defense is provided against liability for failure to warn when a drug or medical device is 'properly prepared, and accompanied by proper directions and warning.'" *Sita v. Danek Medical, Inc.,* 43 F.Supp.2d 245, 259 (E.D.N.Y. 1999) (citations omitted). The manufacturer "satisfies its duty by 'warn[ing] of all potential dangers . . . that it knew, or, in the exercise of reasonable care, should have known to exist." *Id.*

As this case involves a medical product, the learned intermediary doctrine applies. *See, e.g., Fane v. Zimmer, Inc*., 927 F.2d 124, 129 (2d Cir. 1991) (interpreting New York law). Under the learned intermediary doctrine, the defendant manufacturer had an obligation to inform Dr. Suddaby of the risks of using the SSF System. It was then his duty to evaluate Ms. Donovan's needs, assess the risks and benefits of the product, weigh the risks against the advantages available, and then prescribe the product, advising the patient of the risks and possible side effects. *See Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 96 (App. Div. 1979), *aff'd,* 417 N.E.2d 1002 (N.Y. 1980). "Thus, the manufacturer's liability, if any, is directly related to the adequacy of the warning provided." *Id.* If the doctor is sufficiently warned, the product is not defective. *See Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980). Nor is a manufacturer responsible for how a learned intermediary conducts his business. *See Krasnopolsky v. Warner-Lambert Co.,* 799 F. Supp 1342, 1346 (E.D.N.Y. 1992).

Plaintiffs argue that the learned intermediary doctrine does not absolve defendant in this case because the warnings contained in the product insert do not adequately warn the physician of the dangers associated with the SSF System. Specifically, plaintiffs state that defendant's product insert provides that the SSF System is "temporary," yet the term is not defined. Dr. Suddaby testified that the SSF System is intended to be permanent–sometimes the hardware remains permanently in the patient's body following the spinal fusion, but sometimes it is removed. Suddaby Dep., p. 41. Ms. Hillyard testified that the SSF System is "intended to be implanted up until the time the patient reaches a fusion . . . ." Hillyard Dep., p. 45. The product insert also provides that the SSF System is "intended to be removed after solid fusion has occurred," yet removal is not required in every case, with the decision made by the doctor and patient. *Id.,* pp. 45-46. The product insert also provides that use of the SSF System has potential risks that may require additional surgery, including "device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurologic injury, and vascular or visceral injury." Item 75, Exh. G., p. 19. Other fully disclosed complications and adverse side effects include lack of effective treatment of symptoms for which the surgery was intended, and pain and discomfort. *Id.* p. 20.

It is apparent from the deposition testimony and the product literature that the SSF System is a medical device, surgically implanted by a physician, that provides temporary support during the process of spinal fusion, but is not intended to provided permanent support for the spine. The hardware can thus be removed or remain in the patient's body following fusion, depending on the circumstances of each case. Information concerning this product is distributed to doctors rather than directly to the patients. In this case, the

package insert gave detailed information concerning the risks associated with the SSF System including, but not limited to, breakage of the component parts and pain. These are the same conditions about which Mrs. Donovan now complains. When the warning given to the prescribing doctor by the manufacturer through package inserts gives specific detailed information on the risks of the product, the manufacturer has been held absolved as a matter of law. *See Wolfgruber*, 423 N.Y.S.2d at 97. Plaintiffs were made aware of the risks of spinal fusion surgery, including breakage of the equipment, pain, and discomfort, and failure to achieve a solid fusion. Accordingly, assuming for purposes of this motion that the claim for failure to warn was properly pled, plaintiffs' motion for summary judgment is denied, defendant's motion for summary judgment is granted, and the claim is dismissed.

2. Defendant's Motion *in Limine*

Given the court's determination denying plaintiffs' motion for summary judgment, granting defendant's motion, and dismissing the complaint, it is unnecessary to address the defendant's motion *in limine*.

CONCLUSION

Plaintiffs' motion for summary judgment (Item 64) is denied. The defendant's motion for summary judgment (Item 70) is granted, and the complaint is dismissed. The defendant's motion *in limine* is dismissed as moot (Item 79).

So ordered.

_____\s\ John T. Curtin _
JOHN T. CURTIN
United States District Judge

Dated: 3/29/2010
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